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Attn: Mr. John Hebert

January 9, 2011

Re: Supporting materials for amendment application
Rozol Prairie Dog Bait, EPA Reg. No. 7173-286

Dear Mr. Hebert,

Liphatech submitted an amendment application for Rozol Prairie Dog Bait, EPA Reg. No. 7173-286, in December of 2010. This amendment would change from the product label by removing the requirement to place bait "by hand" and would thus allow bait to be placed using mechanical bait dispensing equipment.

The enclosed study is submitted in support of that amendment application. This enclosed study is a statistical analysis of some of the data that was collected during the large scale field study that supports the registration or Rozol Prairie Dog Bait (*"Field Efficacy and Hazards of Rozol Bait for Controlling Black-Tailed Prairie Dogs (Cynomys ludovicianus)"* by Lee and Hygnstrom, 2007, MRID 47333602). Specifically, this is an analysis of the data concerning the locations where bait was observed following baiting operations conducted both by hand and by mechanical bait dispensing equipment. The enclosed statistical analysis was performed by the same scientist who conducted the original field study, Charles Lee.

Liphatech has been informed that a similar analysis, conducted by the same Charles Lee, has already been submitted to you by the Kansas Department of Agriculture, in support of a FIFRA Section 24(c) SLN registration KS-100003, granted by KDA last December. However, Liphatech was not provided with a copy of this earlier analysis by Lee. Liphatech sponsored Charles Lee to produce the enclosed report of his statistical analysis with the intent of making this submission in support of our pending amendment application.

We have now received a copy of EPA's letter to the Kansas Department of Agriculture, dated February 4, 2011, requesting additional information to support EPA SLN No. KS-100003 . This letter asserts that

> "The provided statistical analysis from the Lee and Hygnstrom (2007) study is not necessarily predictive of what would occur under normal, operational use by applicators using mechanical or hand application. The analysis was based on monitoring data from phase of the study that did not have the goal of assessing accuracy of bait placement."

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We strongly disagree with both allegations quoted above. The field study was conducted and documented under EPA's Good Laboratory Practice requirements, and involved applications at a large number of sites over the course of six months. The bait application performed during the study was conducted according to the label instructions, using standard methods and common commercial application equipment, as described in the study protocol and report. The applications were made by several different experienced commercial applicators holding the proper certifications, as well as inexperienced persons working under their direct supervision. We believe that the record shows that the applications were made properly, in the usual and customary manner, and that there is no evidence to support the postulation that that the study "is not necessarily predictive of what would occur under normal, operational use..." In the many reviews conducted by various EPA reviewers of this study, no comment was ever made to suggest that that the bait application was not reflective of normal, operational use.

Contrary to the statement in EPA's letter, the report submitted today is a statistical analysis of data that was specifically collected for the purpose of assessing the accuracy of bait placement. This intention and the procedure used are described in both the protocol and final report of the field trial. The study plan was very clear about our intention to collecting data on bait placement in order to provide information about the availability of bait on the ground surface following routine application. This data was analyzed as such in the review by EPA's EFED Division in their "Chlorophacinone Effects Determination" dated September 29, 2010 and published on the EPA website. Thus, we dispute the statement in EPA's letter that this analysis "was based on monitoring data from phase of the study that did not have the goal of assessing accuracy of bait placement."

Thank you for your attention to this matter. We will be happy to supply additional information as may be needed during the consideration of the study submitted today. Please contact me directly if there is any problem or questions concerning this submission.

Sincerely,

Thomas Schmit
Manager of Regulatory Affairs

cc: Ms. Judith Glass, KDA

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TRANSMITTAL DOCUMENT

Name and address of Submitter:

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Regulatory Action in Support of Which this Package is Submitted:

Rozol Prairie Dog Bait, EPA Reg. No. 7173-286

Transmittal Date: **9 February 2011**

List of Submitted Studies:

Volume 1: Administrative materials
- Cover letter dated February 9, 2011

48387001 **Volume 2: Statisical Analysis of Bait Placement in a Prairie Dog Efficacy Study**
(LTI Number 11019)

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